STAMFORD HEALTH
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Affiliate: Columbia University College of Physicians and Surgeons
A Planetree Hospital
A Magnet® Recognized Hospital

Approved
5/23/19
SHN

VIA ELECTRONIC MAIL
May 21, 2019

Susan Newton, RN
Supervising Nurse Consultant
Facility Licensing and Investigations Section
State of Connecticut
Department of Public Health
410 Capitol Avenue, P.O. Box 340308
Hartford CT 06134

Dear Ms. Newton,

Enclosed is Stamford Hospital's Plan of Correction that is being submitted in response to the alleged violations cited in your letter dated May 7, 2019.
Please note that this submission should not be viewed as an admission of any violation of the Public Health Code or any other statue or regulation.

Should you have questions or need additional information, please contact me at 203-276-7134.

Sincerely,

Maggie Zurita

Maggie Zurita, BSN, RN, CPHRM, CJCP
Director, Regulatory Affairs.
Stamford Hospital

STAMFORD HOSPITAL

Violation Alleged	Risk Reduction Strategy	Person(s) Responsible for Implementation	Date of Implementation	Measurement Strategy
I.*Based on clinical record review, and interview for 1 of 3 patients (Patient #1) the facility failed to have a mechanism to ensure that laboratory results were communicated to the patient. The findings include the following: a. Review of Patient #l's clinic record indicated that the patient was seen at the genetic clinic on 6/1/18. The note indicated that an Ovanext panel would be completed and that it was anticipated that the results would be available in three weeks and that the patient would be contacted to discuss them once available. Review of the clinic record indicated that the results were sent to GC #1 via e-mail on 7/3/18. The report indicated that the patient had had a positive BRCA 1/2 result. The clinical record failed to reflect that Patient # l received notification of the results. Review of facility documentation provided by the Service Line Director identified an email from GC #1 to the administrative assistant dated 7/5/18 that she left a message for Patient #1 and if the patient returned the call to set up an appointment on 7/6/18, with an addendum that indicated that there was free time on 7 /13/18 and to save that time for Patient # 1. The record failed to reflect any further documentation/follow-up and/or confirmation that Patient #1 received notification of the results. Review of the H&P dated 12/30/18 indicated that the patient presented with weakness and	• Focused audit of medical records of all cancer genetic testing cases performed between 1/1/2017 and 12/31/18 where results equaled pending, positive or variant of uncertain significance was undertaken. No other reporting delays were found that impacted patient care. • Prior to this incident, the Hospital hired a physician, who is Board Certified in Obstetrics and Gynecology as well as Medical Genetics. As of January 2019, the Hospital consolidated reproductive and cancer genetics counseling and testing into one division and appointed this physician as Director, Division of Genetics.	• Service Line Administrator, Cancer Services • Quality Manager, Cancer Services	February 2019 through February 2020	• To help ensure that there is no reoccurrence of the event, the Hospital will audit on a random basis no less than 20 patient records per month for the next 6 months, and then 20 per quarter for the next two quarters, for documentation that patient and/or referring providers were informed of results. The target goal of audit is 100% compliance and any deviation from this target will result in additional evaluation and, if needed, further corrective action. • The results of the audits will be

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cough times one month. The patient had a history of hypertension. The H&P dated 1/11/19 indicated that the patient was scheduled for elective surgery on 1/14/19 for an exploratory Lap secondary to an adenocarcinoid tumor. Review of the 1/14/19 operative note indicated that the patient had stage 4 ovarian cancer. The note indicated in part that a total hysterectomy was completed bilateral salpingo-oopherectomy, total omentectomy, and a low anterior resection with end to end anastomosis and protective colostomy. Interview with the Service Line Director on 3/27/19 at 1 :45 PM indicated in December of 2017 the GC had resigned from her position but agreed to stay on in a per diem capacity. The Director indicated that the GC's last day seeing patients was July 13, 2019. The Director indicated that during the investigation the facility was unable to track communication between the GC and the patient and subsequently had information technology review the phone records. Interview with GC #1 on 4/4/19 at 3:00 PM indicated that she met with Patient #1 in June of 2018. The GC indicated that the patient's results came back via secure e-mail the beginning of July and that she attempted to contact the patient several times and recalls subsequently talking to the patient and informing the patient to come in for an office visit on 7 /13/18 for a full discussion. The GC indicated that the	• As of January 2019, the Cancer Genetics program has implemented software for the electronic medical record, which offers enhancements in both scheduling modules as well as documentation templates for office visits, patient telephone encounters, acknowledgement of laboratory testing results, and communications back to referring providers.			reported out at the Cancer Center Quality Meeting.

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patient did not come to the appointment and that 7 /13/18 was her last day and she passed on Patient # 1 's information to the Administrative Assistant. 2. Based on clinical record review, interview and policy review for 1 of3 patients (Patient #1) the facility failed to ensure that a comprehensive clinical record was completed. The finding includes the following: a. Review of Patient #l's clinic record indicated that the patient was seen at the genetic clinic on 6/1/18. The note indicated that an Ovanext panel would be completed and that it was anticipated that the results would be available in three weeks and that the patient would be contacted to discuss them once available. Review of the clinic record indicated that the report was sent to GC #1 on 7/3/18. The report indicated that the patient had had a positive BRCA 1/2 result. Interview with GC #1 on 4/4/19 at 3:00 PM indicated that she met with Patient #1 in June of 2018. The GC indicated that the patient's results came back via secure e-mail the beginning of July and that she attempted to contact the patient several times however failed to document the calls. The GC recalls subsequently talking to the patient and informing the patient to come in for an office visit on 7/13/18 for a full discussion however indicated that she failed to document this in the record. Review of the clinical record failed to	• The documentation for testing and follow up process has been changed to electronic so that all documentation including telephone communication is in one location and is complete.			

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reflect documentation of attempts to contact the patient and/or the outcome. Review of facility documentation provided by the Service Line Director identified an email from GC # 1 to the administrative assistant dated 7 /5/18 that she left a message for Patient # 1 and if the patient returned the call to set up an appointment on 7 /6/18, with an addendum that indicated that there was free time on 7/13/18 and to save that time for Patient #1. The record failed to reflect any further documentation/follow-up. b. Review of the Clinical Genetics Consultation Note dated 6/1/18 indicated that the patient was seen by GC #1 and MD #1. Interview with the Service Line Director on 3/27/19 at 1 :45 PM indicated that MD #1 never saw the patient and that the template used for the note is old. Review of the H&P dated 12/30/18 indicated that the patient presented with weakness and cough times one month. The patient had a history of hypertension. The H&P indicated that the patient had a strong family history of breast cancer (mother and sister). The H&P dated 1/11/19 indicated that the patient was scheduled for elective surgery on 1/14/19 for an exploratory Lap secondary to an adenocarcinoid tumor.				

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Interview with the Service Line Director on 3/27/19 at 1 :45 PM indicated in December of2017 the GC had resigned from her position but agreed to stay on in a per diem capacity. The Director indicated that the GC's last day seeing patients was July 13, 2019. The Director indicated that during the investigation the facility was unable track communication between the GC and the patient and subsequently had information technology review the phone records. Review of the facility correction action plan indicated that an audit was completed of all positive genetic testing results for the previous two years 1/1/17 through 12/31/18 to ensure results were communicated, no reporting delays were identified. A new electronic medical record was implemented that has documentation templates for patient telephone encounters, acknowledgement of test results and communication back to referring provides.				